UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,935	05/04/2005	Rubina Mian	GRT/3772-38	9653

23117 7590 12/01/2009

NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER	
GITOMER, RALPH J	
ART UNIT	PAPER NUMBER
1657	
MAIL DATE	DELIVERY MODE
12/01/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/533,935	MIAN ET AL.	
	Examiner	Art Unit	
	Ralph Gitomer	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5,7-14,16,17 and 24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,7-14,16,17 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

In view of the Petition Decision of 11/5/09, all claims have been rejoined, and the Requirement for Restriction of 8/11/09 is hereby withdrawn. Hence this Office action is made non-final. Rejoined claims 12-14, 16, 17 are directed to stress relieving drugs.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Suzuki.

Suzuki (J of Applied Physiology) entitled "Capacity of Circulating Neutrophils to produce Reactive Oxygen Species After Exhaustive Exercise" teaches in the abstract, testing people after maximal exercise where the capacity of circulating neutrophils to produce reactive oxygen species detected with luminol and lucigenin when stimulated. On page 1215 column 2 first full paragraph compounds used to stimulate the neutrophils to produce superoxide include FMLP, PMA, S. aureus, and zymosan. The response of nonstimulated cells as also investigated.

All the features of the claims are taught by Suzuki for the same function as claimed.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7, 8, 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki.

See the teachings of Suzuki above.

The claims differ from Suzuki in that they specify the subject is an animal rather than a human.

It would have been obvious to one of ordinary skill in the art at the time of the invention to perform the assay as taught by Suzuki on humans and to perform the same assay for the same function on animals because the function of neutrophils in animals would be expected to be the same as in humans. Adapting a known diagnostic for humans to other animals with the expected result would have been obvious.

Claims 12-14, 16, 17 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Suzuki in view of Carlson.

See the teachings of Suzuki above.

The claims differ from Suzuki in that they include screening for drugs and treating the stress that has been measured.

Carlson (6,319,953) entitled "Treatment of Depression and Anxiety with Fluoxetine and an NK-1 Receptor Antagonist" teaches in column 36 screening for anxiolytic activity of drugs by administering the drugs and stressing the animals to determine the efficacy of the drugs. In the abstract treatment of depression and/or anxiety is shown.

It would have been obvious to one of ordinary skill in the art at the time of the invention to screen for drugs for treating stress and then treating the stress as shown by Carlson with the stress determining method of Suzuki because Suzuki teaches a method of determining stress and any known method of determining stress would be expected to work in the method of Carlson. Employing a known method of determining stress for its known function would have been obvious. And treating stress with drugs is old.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 5, 7-14, 16, 17 and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There are a number of confusions in the claims that are not clarified by the specification as originally filed. On page 3 first paragraph of the specification "the ability of neutrophils to respond to such in vitro challenge after a stressful event is defined as the individual's coping capacity. Individuals with a higher coping capacity have greater potential superoxide production and, physiologically, are better able to cope with bacterial challenge after stress." The present claims are directed to determining coping capacity but the specification appears to be directed to a method of determining the amount of stress, not coping capacity. Coping capacity is response to psychological stress has a meaning in this art and as defined in both the specification and claims, the terms are used in a fashion repugnant to the art.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 5, 7-14, 16, 17, 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

Claim 1 defines "coping capacity" in a fashion repugnant to the art. As set forth in claim 1, the controls are confusing. In claim 1 line 6 and all occurrences, "of the same species" is unclear as to what may be intended because no species are claimed. As written, it is unclear as to what controls may be intended. A single sample is obtained so no controls would be seen. In claim 1(c) line 4 "or at least" is not understood in context. In claim 1(c) last line, "subject to the same conditions" does not recite what conditions are intended and lacks antecedent basis. Claim 1(d) is not understood. In claim 1(e) last line "under the same in vitro conditions" lacks antecedent basis because no in vitro conditions are set forth. In claim 1 line 26 "above basal" is not understood and lacks antecedent basis. Further, the phrase "above basal in said test sample compared to in said control sample" does not state what the control sample may be. As set forth, no controls are defined and what is intended by basal is not seen. In claim 1 lines 27-28 "the degree of chemically-induced" is not understood and is improper. In claim 10 "the resulting" lacks antecedent basis. In claim 12 the preamble is directed to a drug but the body of the claim includes no drugs. In claim 12(c) compounds do not have abilities.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Myhre (Biochem Pharm) teaches inducing neutrophils and determining superoxide with luminescent reagents.

Pincemail (2005/0112572) teaches treating oxidative stress.

Shult (J Lab Clinical Medicine) teaches stimulating neutrophils to produce superoxide.

Myhre (Biochemical Pharmacology) teaches indicators for superoxide. Lucigenin and luminol are used in studies of reactive oxygen species.

Mikawa (Canadian Journal of Anaesthesia) teaches changes in superoxide production.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ralph Gitomer/
Primary Examiner, Art Unit 1657

Ralph Gitomer
Primary Examiner
Art Unit 1657